Exhibit 10

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE JOHNSON & JOHNSON DERIVATIVE LITIGATION	**Civil Action No. 10-2033 (FLW)**
IN RE JOHNSON & JOHNSON FCPA SHAREHOLDER DERIVATIVE LITIGATION	**Civil Action No. 11-2511 (FLW)**
COPELAND v. PRICE, *et al.*	**Civil Action No. 11-4993 (FLW)**

REPORT OF DR. MITCHELL GLASS IN SUPPORT OF SETTLEMENT OF THE JOHNSON & JOHNSON DERIVATIVE ACTIONS

I. INTRODUCTION

1. I, Mitchell Glass, under penalties as provided by law, declare that the statements set forth in this Report are true and correct to the best of my knowledge. I am over the age of 21, and have personal knowledge of the facts stated herein.

2. I was retained by derivative plaintiffs' counsel in the Demand Futility Derivative Action, brought on behalf of Johnson and Johnson, Inc. ("J&J" or the "Company"), to assist in the litigation of the derivative claims, including research and analysis supporting the operative pleadings in the case. I was actively involved in the settlement negotiation process, including in the design and drafting of settlement proposals, review of internal J&J documents provided in connection with the settlement negotiation process and attendance at a meeting with, among

others, J&J's Chief Quality Officer, Kathryn Wengel, where I, among other things, made a detailed presentation regarding plaintiffs' proposal related to product risk management.

3. I have been asked by plaintiffs' counsel to review the proposed settlement terms including, but not limited to, the adoption of the Compliance and Quality Core Objective, the adoption of the Product Risk Management ("PRM") Standard, to be implemented during 2013, and the adoption of the Charter and Operating Procedure for the newly formed Regulatory, Compliance and Government Affairs Committee ("RCGC") of the Board of Directors ("Board"), and to offer an expert opinion on whether these and the other terms of the proposed settlement offer substantial benefits to J&J and its shareholders.

4. In my opinion, as set forth below, these provisions, and other aspects of enhanced enterprise risk management ("ERM") set forth in Exhibits A and B, provide substantial governance reforms directed at both the board and management levels of J&J. These reforms, if implemented faithfully, will provide substantial benefits to J&J and its shareholders, including in the detection and prevention of the types of underlying issues alleged in the Amended Complaint.

II. BACKGROUND AND QUALIFICATIONS

5. I am a medical doctor who received a B.A. Special Honors in Biology from the University of Chicago in 1973, and a M.D. from the University of Chicago in 1977. I have completed a residency in internal medicine, a fellowship in pulmonary and critical care medicine and a post-doctoral fellowship in respiratory physiology, all at the University of Pennsylvania and affiliates. In addition, I have been an Assistant Professor of Medicine and Physiology at the University of Pennsylvania, and have acted as an Attending Physician at the Pulmonary Section, Graduate Hospital in Philadelphia, Pennsylvania. I have a specialty certification from the

American Board of Internal Medicine in Internal Medicine, and a sub-specialty certification in Pulmonary and Critical Care Medicine.

6. I have had extensive experience in the pharmaceutical industry, including work with ICI Pharmaceutical Group and Zeneca PLC, and as a Vice President and Director, CardioPulmonary (Pulmonary/Diabetes) Therapeutic Unit Clinical Research, Development and Medical Affairs at SmithKline Beecham Pharmaceuticals. At SmithKline Beecham, I was responsible for managing a budget for over $150 million. a team of fifty-five personnel, and oversaw all aspects of Phase 2 through Phase 4 clinical trial studies across a range of over twenty drugs and drug candidates.

7. For five years, I acted as the Chief Medical Officer and Senior Vice President Strategic Drug Development, Clinical Development and Regulatory Affairs of AtheroGenics, Inc., with responsibility for a budget of $20 million. While at AtheroGenics, I was responsible for the filing of five Investigational New Drug ("IND") applications, and acted as the senior representative to both the FDA and the equivalent Canadian regulatory authority. I established and managed a new development department that included Development Chemistry, Toxicology, Drug Metabolism and Biometrics/Data Management, Clinical Research and Safety, Regulatory Affairs and Quality Assurance, and was the Chairman of the Pharmaceutical Review Board for integration of Research and Development at the Company. I managed the introduction of quality systems into all aspects of AtheroGenics, as well as the development of its lead compound from IND through to initiation of Phase 3 clinical trial studies for atherosclerosis.

8. I have also served as a Director of the Board, President and Chief Operating Officer of geneRx+ (a start-up biotech company), and Chief Executive Officer and a Director of

Aqumen NA, Inc., a Japanese ophthalmic biotech company. At Aqumen, I successfully initiated both an IND and Phase 3 clinical trial program for the company's lead compound.

9. I presently work as CEO of Axeuron, Inc., a private biotechnology company focused on smoking cessation, as President and Director of Inverseon, Inc., which has Phase 2 clinical trial programs in asthma and chronic bronchitis, as Chief Medical Officer and Director of OrphaGeniX, Inc., focused on using targeted gene editing to cure sickle cell anemia, and as a consultant to start-up pharmaceutical and device companies.

10. For the past 10 years, I have directed a course to introduce to physicians and scientists the precepts of drug development, (PERI course DDMS-1) including concepts of Good Manufacturing, Laboratory and Clinical Practices, regulatory affairs and integration of knowledge learned from chemistry and animal toxicology into clinical development and strategic decision making.

11. Over the course of my career, I have actively interacted with the FDA and other regulatory authorities in the U.S. and abroad across a variety of drug and drug treatments, from inception through approval and launch. I also developed new integrated development teams at three companies. My teams have filed more than 45 IND applications and had 5 drugs approved.

12. I have written over thirty-five papers or abstracts on topics related to medicine, drug development and basic science. I have attached a copy of my Curriculum Vitae as Exhibit 1 to my Report.

III. SUMMARY OF OPINION

13. In my opinion, the terms of the settlement, including the Exhibit A provisions requiring the adoption of the Quality and Compliance Core Objective, the Board's agreement that the Regulatory, Compliance & Government Affairs Committee ("RCGC") will operate with

the rigorous oversight responsibilities and duties related to compliance and quality set forth in the Charter and the Operating Procedure, and the adoption of the PRM Standard, will provide substantial benefits to J&J and its shareholders, and will place J&J at the forefront of best practices with respect to product risk management. As described below, adoption of PRM is an essential step in the effective implementation of a comprehensive risk prevention and mitigation strategy.

14. These provisions, adopted as a result of the proposed settlement, are critical, and, in my view, effectively address the alleged wrongdoing and problems at J&J that underlay the Derivative Actions. The adoption of the Quality and Compliance Core Objective and the RCGC Charter and Operating Procedure will, in my opinion, provide for enhanced knowledge and responsibility of the Board; result in a more actively engaged Board; and help assure the prevention of issues and problems that can cause reputational harm or result in violations of law, regulations or J&J polices and standards in the future.

15. As designed, the proposed PRM Standard, once implemented at J&J, will effectively ensure the early identification, timely remediation and accountability for resolution of product issues at the Company. In addition, the PRM Standard will also address the escalation process for identified issues, including up the Quality organization as appropriate. In specific, the settlement provides for the prompt assignment of functional responsibility for resolution of product issues and problems identified at any level of the enterprise; mandates the tracking of identified issues through resolution, based on established timeframes, thereby preventing their becoming sidelined or remaining unresolved indefinitely; and imposes an escalation process that will include both notification once the issue is identified, and for elevating responsibility up the

J&J organization[1] for issues that are unresolved within established timelines or for which a determination is made that timely resolution (including, for example, for situations that may require further data collection and analysis or resource re-allocation) requires the involvement of a higher authority without delay. Moreover, the PRM Standard under the proposed settlement critically provides that the process of issue resolution, including monitoring, escalation and intervention will be managed by the independent Quality organization, under the control and oversight of the J&J Chief Quality Officer ("CQO").

16. In addition, other provisions set forth in Exhibits A and B, as discussed below, provide additional substantial benefits to the Company and, when combined with the above benefits, should materially strengthen J&J's corporate culture and re-establish J&J's reputation of excellence within the pharmaceutical industry in areas of governance, compliance and risk management.

[1] The J&J organization is comprised of more than 250 operating companies in 57 countries. J&J follows a decentralized operating model which directs control and operational responsibility at the individual operating company level. There are three business sectors at J&J: Consumer, Pharmaceutical and Medical Devices & Diagnostics. Each sector has a World Wide Chairman. Operating companies are led by company chairmen, presidents, general managers or managing directors, who report directly or through a line executive to the sector World Wide Chairman. Above the sector level is the J&J corporate level. Relevant to this settlement, the J&J Chief Quality Officer ("CQO") and J&J Chief Compliance Officer ("CCO") are at the corporate level. As detailed herein, Chief Quality Officers and Health Care Compliance officers have been appointed at the sector level (see Exhibit B, Sections II.C.4. and II.D.3, respectively). J&J also has quality and compliance personnel at the operating company level. Pursuant to the proposed settlement, under the PRM Standard, Quality personnel will now have responsibilities at the product team level in connection with the implementation of the PRM Standard (described at Section IV.C.2. below). The quality function, from the J&J CQO, through the sector CQOs, down to the operating company level and now including at the product team level, is referred to herein as the Quality organization.

IV. REFORMS UNDER EXHIBIT A OF THE PROPOSED SETTLEMENT

17. In the following paragraphs, I discuss in detail major components of the proposed settlement, in particular the Quality and Compliance Core Objective, the Charter and Operating Procedure for the newly formed RCGC and the PRM Standard, and how their adoption at J&J under the proposed settlement provides substantial benefits to the Company and its shareholders.

18. As I discuss below, the Quality and Compliance Core Objective, the RCGC Charter and Operating Procedure and the PRM Standard are designed to operate, in conjunction with the reforms set forth in Exhibit B, as an integrated system of quality and compliance control. When fully implemented, these systems will create a powerful set of checks and balances, providing the reporting and accountability necessary to support the robust oversight obligations the Board has undertaken pursuant to the settlement. Taken together, these reforms will focus J&J resources at all levels on the critical tasks of prevention and early intervention.

A. Adoption of the Quality and Compliance ("Q&C") Core Objective

19. As a result of the proposed Settlement, J&J has agreed that the Board will adopt a resolution establishing the Q&C Core Objective. The Q&C Core Objective requires the Company to affirm its resolve to operate its businesses, sectors, entities and franchises:

(i) in compliance with applicable laws, regulations and Johnson & Johnson policies and standards;

(ii) to deliver high quality products that patients and providers can trust;

(iii) to conduct its activities and have policies and procedures in place so as to minimize adverse regulatory enforcement action; and

(iv) to maintain, enhance and support effective quality and health care compliance systems designed to promptly detect, correct and prevent activities violative of applicable laws, regulations and/or Company policies and standards.

See Exhibit A, Section I. The Q&C Core Objective further requires that:

> Johnson & Johnson will adopt and/or maintain policies, procedures and standards to ensure the effective implementation of the Quality and Compliance Core Objective. The Company will design and/or maintain robust quality control and quality assurance systems to prevent, detect and correct noncompliance with the Quality Policy and standards within Johnson & Johnson, including tracking remediation against established timelines. These quality systems will be subject to benchmarking and metrics that will evolve to reflect successful implementation of the Core Objective. The Company will design and/or maintain robust systems to actively monitor for, and prevent or remedy breaches of internal J&J policies and standards and regulatory or legal compliance in the areas of quality and health care compliance. The Company's compliance systems will provide the resources and information necessary to review, escalate and resolve issues arising from the development or marketing of Johnson & Johnson products. Compliance with applicable laws, regulations, and internal policies, procedures and standards will be reviewed regularly throughout the life-cycle of products, including those related to the marketing and promotion of drugs and devices.

Id. In my opinion, the adoption of the Q&C Core Objective by the Board is critical for J&J going forward and, as discussed below, provides substantial benefits to the Company and its shareholders.

20. First, through the Board's adoption of the Q&C Core Objective, the Board recognizes, in a manner that is unambiguously made clear enterprise-wide at the Company, its oversight obligations and responsibilities with respect to the expanding role of independent compliance and quality functions within J&J. Further reflecting this expansive role, and the Board's explicit oversight responsibilities in connection with it, the Charter and Operating Procedure for the newly formed RCGC (adopted pursuant to the settlement and discussed in Section IV.B. below), establish mandatory reporting from key functional corporate officers and executives, including the CQO and J&J Chief Compliance Officer ("CCO"), to ensure adequate

and timely information flow about these and other critical functions up through the enterprise and to the Board.

21. Second, the Board expressly recognizes its oversight responsibility in support of the adequacy of the compliance and quality assurance functions at J&J, which includes oversight of resource allocation to those functions. *See, e.g.*, Exhibit A, Section I ("The Company's compliance systems will provide the resources and information necessary to review, escalate and resolve issues arising from the development or marketing of Johnson & Johnson products."). This responsibility is also expressly provided for in the RCGC Charter and Operating Procedure (*see, e.g.*, Section IV.B.5. below). In my opinion, based on my experience and expertise in the pharmaceutical industry, the Charter and Operating Procedure recognition and effectuation of this responsibility at the Board level, combined with the oversight responsibilities directed to resource allocation reflected in the Q&C Core Objective, provide a significant benefit under the settlement. To comply with these responsibilities, the Board will be provided data and metrics regarding resources, including as related to personnel, money (budget) and time. The information provided must be adequate to allow the Board to assess whether allocated resources are sufficient to meet the ambitious compliance and quality plans, programs and organizations at J&J. This Board-level oversight of resources protects these critical functions, ensures their robust resources and sends an important message to the enterprise regarding tone at the top recognition of their importance at J&J.

22. Third, the Board expressly recognizes its oversight responsibility related to the prevention, detection and resolution of quality and compliance issues and problems in connection with *all* activities of the enterprise over the entire life cycle of J&J products. Thus, the Board's oversight will include not only over those issues that violate laws or regulations, but

also those that violate J&J policies and standards,[2] and which, if left unchecked, could rise to the level of causing regulatory violation or reputational harm. Critical to meeting this oversight responsibility will be the implementation of the PRM Standard under the proposed settlement, which, in my opinion, for the reasons set forth at Section IV.C. below, will become the framework for effective product risk mitigation and prevention at the Company going forward. The PRM Standard will be implemented under the control of the CQO and the Quality organization. As noted above, the settlement imposes rigorous reporting obligations on the CQO to the RCGC (and through it, the entire Board), which will include information directly related to the implementation and effectiveness of the PRM Standard at the Company, and thus actively supports compliance with this goal of the Q&C Core Objective. *See e.g.*, Sections IV.B.2., 3. 4, and 8. below.

23. Fourth, the Board explicitly recognizes that the Q&C Core Objective mandates that quality and compliance systems, standards and procedures put into place at the Company must include the requirement, capability, and enabling authority to address issues in a timely manner, *i.e.*, as they arise. J&J's commitment to prevent and to timely remediate issues is a fundamental corporate concept and its adoption throughout the enterprise will be far-reaching in effect. In my opinion, one of the major problems J&J faced during the relevant period of the Derivative Actions was that, due to its decentralized organizational structure and commercial pressures, significant product issues became mired at the individual operating unit level rather than being elevated up the J&J organization for timely resolution. In support of this requirement of the Q&C Core Objective, the proposed settlement commits J&J, through the CQO function, to design and implement the PRM Standard, which will address, among other things, the

[2] Standards set the specifications that must be met under applicable policies, that are then effectuated by operating procedures ("SOPs").

requirement to develop resolution timelines and action plans for identified product issues, as well as quality metrics for evaluating issue resolution, including tracking remediation of issues against established timelines. *See e.g.*, Section IV.C.4. below. The Board, through the RCGC, pursuant to the Quality and Compliance Core Objective, as fully supported by the adoption and implementation of the PRM Standard, will now be required to be aware of and have oversight responsibility that appropriate timelines associated with the identification and remediation of quality and compliance issues are established, regularly reviewed and subject to continuous improvement.

24. Fifth, the Board is required to ensure that the Q&C Core Objective will be provided to, and become the responsibility of, every employee at the Company. *See, e.g.*, Exhibit A, Section II ("Following its adoption by the Board, the Quality and Compliance Core Objective will be disseminated in a Johnson & Johnson-wide communication."). The requirement for at least annual enterprise-wide communication from Corporate about the Q&C Core Objective (*see id.*, ("A similar communication will be disseminated enterprise-wide on an annual basis thereafter, and the Quality and Compliance Core Objective will be provided to new employees.") directly impacts tone at the top and the perception by rank and file employees of J&J regarding its importance. Every employee will be responsible for understanding the importance of prevention and timely correction of problems when identified. Thus, global individual responsibility will become the standard for the prevention and timely remediation of problems at the Company.

25. Further strengthening the importance and effective implementation of the Q&C Core Objective, the settlement expressly provides that employees will be "instruct[ed] that adherence to and furtherance of the Quality and Compliance Core Objective is to be considered

in the evaluation and compensation of all Johnson & Johnson employees." Exhibit A, Section II. In my experience in the pharmaceutical industry, one of the most effective ways to ensure directives from the top are embraced and adhered to below is to tie individual employee compensation to compliance with such directives and tie the compensation of management to the successful implementation of such directives throughout their functional areas of responsibility. J&J will create this important linkage between a strengthened corporate culture and compensation under the proposed settlement. *See also* a discussion of role of the RCGC and the Compensation and Benefits Committee of the Board in connection with this provision at Section IV.B.10. below.

B Adoption of the Regulatory, Compliance & Government Affairs Committee ("RCGC") Charter and Operating Procedure

26. In my opinion, it is essential that the Board receive direct, complete and regular reports and updates on the progress of the Company's activities, both with respect to specific issues or concerns that have arisen, and with respect to the compliance and quality systems, standards and procedures established to prevent such issues and/or to minimize their impact on the Company and its operations. This essential requirement is a core provision of the settlement, which sets forth the responsibility of the newly formed RCGC, through the adoption of the Charter and Operating Procedure set forth at Exhibit A, to oversee matters involving regulatory, compliance, quality, and governmental affairs that may impact J&J, and provides for regular and detailed reporting from critical functional officers at the Company.

1. Scope of Oversight Responsibility

27. The Charter sets forth explicit responsibility to the RCGC over non-financial compliance at J&J, listing among the Committee's specific duties and responsibilities, the requirement to:

> [o]versee the Company's major compliance programs with respect to regulatory requirements (including, but not limited to, the Company's policies and procedures for monitoring health care compliance, including HCC&P programs and policies; product quality and compliance, including Q&C programs and policies; product safety; privacy; environmental regulation; employee health and safety; and compliance with the U.S. Foreign Corrupt Practices Act of 1977, as amended), except with respect to matters of financial compliance (*i.e.*, accounting, auditing and financial reporting), which are the responsibility of the Audit Committee.

Charter, "Duties and Responsibilities of the Committee," ¶ 1.

28. This responsibility includes oversight of compliance related to all J&J products throughout their entire life cycle. The RCGC Charter and Operating Procedure commit the Committee, with reporting to the full Board, to knowledge of and direct oversight responsibility for issues of compliance with regulations, policies and standards affecting products, both in development and in the marketplace. In my view, this expansive scope of compliance oversight responsibility constitutes best practice for a board committee of a major pharmaceutical company, and provides a substantial benefit to J&J and its shareholders.

2. Reporting Requirements

29. The RCGC Charter and Operating Procedure are designed to ensure that the Board is fully and regularly informed by designated operational and functional members of J&J's senior management, is kept abreast of the evolution of J&J's quality and compliance programs, and is regularly updated about the adequacy of the systems and resourcing in the compliance and quality organizations. This important goal will be achieved in multiple ways under the proposed settlement.

30. Pursuant to the Charter, the CCO, CQO and Vice President Chief Internal Audit ("V.P. CIA") have guaranteed direct access to the RCGC and its chairman (*see* Operating Procedure, ¶ 6), and the RCGC is required to hold separate, private meetings at least semi-

annually with these critical officers and senior executives, as well as with the J&J General Counsel (*see* Charter, "Meetings of the Committee," ¶ 2). To protect the independence of the CCO, CQO and V.P. Supply Chain,[3] the Operating Procedure provides that the RCGC shall be promptly notified of decisions and actions related to the appointment and/or termination of, or material compensation changes for these critical executives. *See* Operating Procedure, ¶ 5.

31. These provisions offer protection to these executives who may, from time to time, be forced to advocate positions or raise issues unpopular with operational aspects of J&J, where enormous commercial pressures exist. In addition, these provisions make an unambiguous statement to the entire J&J enterprise regarding the importance to J&J and its Board of these officers and executives and their ability to perform their expanded duties independent of financial considerations. Such unambiguous "tone at the top" actions can have an enormous positive impact on the culture of a pharmaceutical company.

32. Robust reporting to the RCGC is a core principle under the proposed settlement. Thus, pursuant to the settlement, the RCGC commits on at least an annual basis, and on a quarterly basis for critical compliance, quality and internal audit functions, to receive comprehensive reporting regarding specifically delineated topics. *See, e.g.*, Operating Procedure, ¶ 3a., b. and c. The Board, through the RCGC, will thus receive the necessary reporting with respect to all aspects of product risk management to support its oversight responsibility. The RCGC will have direct oversight responsibility to ensure that product-related issues are addressed and resolved according to the highest quality and compliance standards, and that these best practices are applied enterprise-wide. The Board, through the RCGC, will have oversight responsibility for issues that could cause safety concerns, regulatory

[3] Under J&J's corporate structure, the CQO reports to the V.P. Supply Chain.

actions or reputational harm, and, as appropriate, will be tracking unresolved issues directly, and on a no less than quarterly basis. The Board will also have oversight responsibility to ensure that there are adequate resources to support robust implementation of all quality and compliance systems, including the PRM Standard, and to develop a culture of problem prevention. The RCGC will be knowledgeable about quality and timeline metrics, which will be reported to them regularly, and will ensure adequate resources to meet them. In my opinion, these responsibilities of the Board and the RCGC, together with the reporting requirements described in the Charter and the Operating Procedure, provide the crucial foundation to support the robust implementation of PRM and to empower key executives, including the CCO, CQO and Sector CMOs, within the organization.

33. In addition, based on my personal experience, reporting to the board of directors of a pharmaceutical company is considered a major and highly significant event. The settlement's robust reporting requirements to the Board will thus assure that senior most management, including the Executive Committee at J&J, will also be fully and timely apprised of information and reporting to be provided to the RCGC under the terms of the proposed settlement.

34. Recognizing that compliance and quality problems can arise at any time, and that the failure to address significant problems in a timely manner can have severe consequences, the Operating Procedure further provides that in addition to the required quarterly reporting, the CCO, CQO and V.P. CIA will also report directly to the chairman of the RCGC promptly regarding substantial matters which arise within their functional areas on an interim basis. *Id.* For example, as occurred in connection with Scios' sale of Natrecor, an operating company at J&J receives an unexpected and negative opinion from a select group of experts concerning the

safety, efficacy or promotion of an important J&J drug. Such an event would trigger an interim report to the Chair of the RCGC.

35. The Operating Procedure details the scope and nature of mandatory reporting, which is designed to inform the Committee (and through it, the full Board) about issues that both arise internally (such as off-label promotion) and externally, such as, for example, new regulation regarding safety reporting or guidance to study an impact of a drug or device in a way not previously required.

3. Effectiveness Assessment Reporting to the RCGC

36. A compliance or quality program or system, like a new drug or medical device, must be assessed repeatedly for effectiveness or it provides little value to the company. Recognizing this crucial concern, mandatory reporting to the RCGC from the CCO also includes reporting regarding the organization, implementation and effectiveness of the Company's compliance programs (*see* Charter, "Duties and Responsibilities," ¶ 3), and from the CQO regarding the organization, implementation and effectiveness of the Company's quality and compliance programs (*id.*, ¶ 4), including regarding the specific implementation and effectiveness of the Quality Policy and its operational Standards.[4] *See* Operating Procedure, ¶ 3.b. In my opinion, information provided pursuant to the adoption and implementation of the PRM Standard at J&J will provide a principal support for this effectiveness assessment of quality programs. If, for example, a recommended FDA label change is not addressed within established timelines, the CQO and CCO will report to the RCGC about the regulatory and safety risks. The Board, through the RCGC, fully informed regarding the FDA recommendation, will have oversight responsibility for the decisions taken in connection with the product . In my

[4] The Quality Policy and Standards are set forth in Exhibit B of the proposed Settlement, and discussed at Section V.C. below.

opinion, PRM will provide not only for this ongoing, timely reporting, but also for the subsequent assessment of the functioning of the system, including of these types of specific decisions and their impact on product quality and delivery. I believe that this type of assessment will become a core element of the CCO and CQO effectiveness assessment and reporting to the Board.

4. Reporting Regarding Quality and Compliance at Newly Acquired Companies

37. The Charter also sets forth oversight responsibility on the RCGC regarding the effective implementation of quality and compliance programs at newly acquired companies, to be supported through mandatory reporting from the CCO and CQO. *See* Charter, "Duties and Responsibilities," ¶¶ 3 and 4. This provision is of particular importance to J&J for several reasons. Over its history, J&J has actively acquired smaller companies. Since smaller companies frequently have neither the resources nor the priority to provide robust systems for quality and compliance, and may not have any quality and/or compliance systems in place, this oversight responsibility at the level of the Board places J&J at the forefront of major pharmaceutical companies. Moreover, given that newly acquired companies will likely maintain substantial autonomy and independence within J&J's decentralized organizational structure, directing responsibility under the settlement to the RCGC regarding oversight of quality and compliance functions at these entities upon their acquisition is critical.

38. In my view, this provision directly addresses wrongdoing at J&J alleged in the derivative complaints, including, for example, allegations regarding the off-label promotion of Natrecor. Natrecor was the only marketed product of Scios, for which J&J paid a significant premium (30%) and price ($2.4 billion) based on Natrecor sales. Plaintiffs allege that Scios actively engaged in off-label promotion of Natrecor for outpatient treatment of chronic heart

problems, and that this outpatient off-label promotion continued, and even expanded following J&J's acquisition of Scios in April 2003, after which the company continued to operate as a separate entity within J&J's corporate structure. In my opinion, providing for express Board oversight responsibility of the organization, implementation, effectiveness and adequacy of resources for compliance and quality programs at newly acquired companies offers the significant benefit of preventing the recurrence of the type of problems alleged in the Amended Complaint suffered by J&J as the result of its acquisition of Scios.

39. The CCO and CQO will be obligated to ensure that adequate and appropriate quality and compliance systems and programs, including the PRM Standard, are instituted according to schedule at newly acquired companies such as Scios. In my view, these responsibilities and written commitments (*e.g.*, schedule for adoption of the PRM Standard) make it unlikely compliance or quality problems, including, for example, pervasive off-label marketing activities occurring at such companies pre-acquisition, will be allowed to continue and may, in fact, affect future decisions on whether to acquire an asset as the importance of quality and compliance at J&J is further elevated. Therefore, imposing on the RCGC oversight responsibility for the implementation and effectiveness of those compliance and quality programs at new companies sends a clear message, and adds substantial benefit to the Company and its shareholders.

5. Resource Allocation Oversight Responsibilities

40. J&J is a complex commercial enterprise. In any commercial operation, the allocation of resources is an essential function. While compliance and governance systems and processes are, in my opinion, critical to the long-term financial strength of this large and complex company, they may be viewed in the short-term as a lower priority or hindrance to

profits, which explains why: (a) small companies under consideration for acquisition may have forgone quality and compliance activities; and (b) in a decentralized corporation, robust quality and compliance activity, supported by tone at the top is even more important. Employees at every level and analysts externally scrutinize resource allocation, which can often have the single largest impact on what corporate culture develops at a company.

41. In my opinion, the robust oversight responsibilities of the RCGC related to resource allocation to compliance and quality functions under the proposed settlement are of major importance, and are likely to have far-reaching impact at the Company. The Charter and the Operating Procedure assign specific oversight responsibility to the RCGC for the adequacy of resources for all compliance and quality programs (*see, e.g.*, Charter, "Duties and Responsibilities of the Committee," ¶¶ 3 and 4; Operating Procedure, ¶¶ 3.a. and b.), as well as for the adequacy of resources for the critical annual audit plan in relevant areas. *Id.*, ¶ 3.c. In addition to these responsibilities over the adequacy of resources for critical functions, the settlement separately also requires that J&J spend such funds as are necessary to implement and maintain the Governance Reforms set forth in Exhibit A and the Governance Enhancements and Changes set forth in Exhibit B in their entirety for a five year period from the Effective Date of the settlement. *See* Section VI. below.

6. Internal Audit Oversight Responsibilities

42. In the area of internal audit, the Charter requires the Committee to review and approve the Company's internal audit plans related to compliance and quality. *See* Charter, "Duties and Responsibilities," ¶ 11. The Company's internal audit process provides a critical check and balance, offering an "independent" assessment by the Internal Audit Department of how well and effectively programs and processes have been implemented and are operating at

J&J. By definition, in a huge multi-national company like J&J, all relevant programs and processes cannot be audited every year or even every several years. Therefore, the determination of which compliance and quality programs and processes are to be audited in any given year, and why, is a critical one. I believe this Charter provision therefore offers a substantial benefit to J&J and its shareholders by requiring that the Board, through the RCGC, assume a direct role in reviewing and approving relevant aspects of the Company's internal audit plans each year, helping to assure that the audit includes the areas of highest risk or potential importance to the Company going forward.

43. As a further element of reporting from the V.P. CIA, the Charter provides that the RCGC will oversee the Company's *Policy on Business Conduct* and *Code of Business Conduct & Ethics of the Board of Directors and Executive Officers*, and, in support of this responsibility, that the V.P. CIA shall at least annually report to the Committee "on significant actual and alleged violations of such Policy or Code, including any such matters that involve criminal or potential criminal conduct." Charter, "Duties and Responsibilities of the Committee," ¶ 6. This requirement provides yet another directed source of reporting to the Committee and the Board regarding issues that could have an adverse effect on the Company and its reputation if left unchecked, a failure at the core of plaintiffs' allegations of longstanding misconduct at J&J.

7. Critical Preventive Oversight Responsibilities

44. In my view, one of the single most important contributions of this settlement is in its focus on prevention of issues *before* they become major problems. This goal is reflected in the Q&C Core Objective (*see, e.g.*, ¶ 22 above), the design of the PRM Standard (as detailed below), and the Charter and the Operating Procedure responsibilities of the RCGC.

45. In addition to the central reforms discussed above, the Operating Procedure provides that the RCGC receive separate reporting from the CCO, the CQO and the V.P. Supply Chain regarding, among other topics, trends affecting the Company in his or her respective area, and, "as appropriate, plans of action to respond to such trends from a preventive standpoint." *See* Operating Procedure, ¶¶ 3. a., b. and d. In addition, the Charter places responsibility on the RCGC to oversee the Company's exposure to risk relating to regulatory compliance, Health Care Compliance & Privacy ("HCC&P") and Quality & Compliance ("Q&C") matters, and requires the Committee to review and evaluate new developments and current and emerging trends relating to regulatory compliance, quality and government relations that affect or could affect the Company. *See* Charter, "Duties and Responsibilities of the Committee," ¶¶ 10 and 13. For example, the CCO and CQO may report that there were 25% fewer warning letters across the enterprise compared with the same quarter a year earlier and 50% fewer compared with 2 years earlier, reflecting the successful implementation of PRM, *i.e.*, the timely intervention and resolution of regulatory recommendations prior to escalation to Warning Letters.

46. These provisions, combined with the obligations under the Charter and the Operating Procedure for comprehensive annual, quarterly and even more frequent reporting by, among others, the CQO, CCO and V.P. CIA (as detailed at Section IV.B.2.above), will support the RCGC in meeting its preventive oversight responsibilities under the proposed settlement. I believe that the more the Company directs its efforts to preventive measures, the stronger those measures will become. In my opinion, vesting the Board, through the RCGC, with express oversight responsibility in this regard is critical to the success of these efforts at J&J, and is an important benefit of the proposed settlement.

8. Medical Safety Reporting

47. The Operating Procedure requires that at least annually, the Committee shall receive reporting concerning medical safety and related quality issues, which will include a review of quality and safety issues impacting each Sector at J&J, to be presented by the respective Sector CQO and Chief Medical Officer (or the equivalent). *See* Operating Procedure, ¶ 3.e. Medical safety issues have special significance to life sciences companies like J&J, as products inevitably generate safety concerns through development approval, and marketing as their uses expand, as the exposure of unstudied populations expands, and as the new product is used in combination with different drugs. Therefore, having the Board of a major drug company like J&J take direct oversight responsibility of this area is especially critical.

48. The Chief Medical Officer's reporting responsibilities to the RCGC under the proposed settlement will include the pharmacovigilance process[5] in place at J&J sectors. Medical safety problems, both proven and unproven, can be extremely damaging, particularly if subsequently confirmed only after the product or drug has been made much more broadly available. The massive product recalls at J&J fully support this observation. The public's strong adverse reaction against the products involved in the recalls resulted in hundreds of millions of dollars in losses, and huge reputational damage to the J&J image and public perception.

49. By requiring Board reporting on medical safety issues, the proposed settlement goes a long way to assure the pharmacovigilence processes at J&J, and the data collected to support them, are robust, effective and geared towards prevention. Furthermore, in my opinion, the type of medical safety reporting provided for under the proposed settlement will help to ensure that the Board better understands the evolution of benefits and risks of J&J products in

[5] At pharmaceutical companies, the pharmacovigilence function is responsible for product and product candidate safety.

development and in the marketplace, and is satisfied that the enterprise is adequately resourced to address these issues in a timely and effective manner. Taken together with the reports of the CCO and CQO, the reports of the CMOs and V.P. CIA will act as complementary sources of risk identification and reporting on nascent issues within their areas of responsibilities.

9. Adequacy/Effectiveness Self-Assessments by the RCGC

50. The Charter requires that the RCGC cannot simply rely on the scope and nature of reporting provided to it, but rather has the responsibility at least annually to assess the adequacy of the reporting and information provided to it by management to support the Committee's oversight responsibilities. *See* Charter, "Oversight of Committee Matters," ¶ 3. In addition, the Committee must conduct an annual evaluation of its own performance in fulfilling its duties and responsibilities under the Charter (*id.*), and must review and assess the adequacy of the Charter and recommend any proposed changes to the Board for approval. *Id.*, ¶ 4. These provisions, in addition to making the Committee and the Board more forward looking and aware in outlook, also act to invest and actively engage the RCGC in fulfilling its essential oversight responsibilities.

10. Coordination with the Compensation and Benefits Committee

51. The provision (discussed at ¶ 25 above) that adherence to and furtherance of the Q&C Core Objective are to be considered in the evaluation and compensation of all J&J employees, is enforced by the Charter requirement that the RCGC will consult with the Compensation and Benefits Committee regarding the application of the Q&C Core Objective in employee performance evaluations and compensation. *See* Charter, "Duties and Responsibilities of the Committee," ¶ 12. Investing the time and oversight responsibilities of two Board-level committees to achieving this requirement of the proposed settlement again sets

a critical tone at the top at the Company, and assures the emphasis on this provision (and the corporate culture it supports), does not wane at J&J as memories of the current problems fade.

C. Design and Implementation of the Product Risk Management ("PRM") Standard at J&J

52. As reflected in the Amended Complaint filed in the Derivative Actions, as well as in the press and regulatory actions, J&J, a giant and long-term leader in life science products, has faced issues and problems across all classes of products it manufactures.[6] As noted above, life science companies are particularly sensitive to reputation, and the problems J&J has experienced have had a direct impact on the public's perception of the Company, as evidenced by, among other facts, J&J's removal from the *Forbes* List of America's Most Admired Companies in 2011, and its failure to regain that coveted position in 2012.

53. Plaintiffs alleged that problems at J&J were allowed to remain unresolved at business units (lower level operating entities), a situation plaintiffs contend was exacerbated by the Company's decentralized corporate structure. Alleged problems (as detailed in the Amended Complaint) included, for example, the active off-label promotion of Risperdal that continued for years at Janssen, the prolonged off-label marketing of Topamax at Ortho-McNeil, and, as noted above, the active off-label promotion of Natrecor at Scios, both before and after its acquisition by J&J. Similarly, alleged knee and hip joint replacement kickbacks were paid by DePuy, where efforts were also made to protect the ASR hip replacement device franchise despite mounting evidence of product failure rates incompatible with safe and effective use. In addition, pervasive alleged off-label promotion of biliary stents went on at Cordis for years. Plaintiffs also alleged that serious problems and violations of FDA current Good Manufacturing Practices (cGMP)

---

[6] J&J is a global leader in all three of the general classes of products it manufactures: pharmaceuticals, devices and diagnostics, and over-the-counter (or non-prescription) health aids.

were allowed to develop and remain unresolved at manufacturing facilities in Pennsylvania and Puerto Rico, despite repeated warnings and adverse findings by regulators, which resulted in massive product recalls, costing the Company hundreds of millions of dollars in lost sales and enormous reputational damage.

1. The Preventive Impetus of PRM

54. In my opinion, the adoption of the PRM Standard at J&J pursuant to the proposed settlement directly addresses major problems plaintiffs allege occurred at the Company, and is designed to identify issues as they occur and to prevent the recurrence of similar problems. As described in detail below, I believe PRM will provide at least four far-reaching benefits. First, the PRM Standard explicitly provides a major tool for achieving the preventive requirement of the Q&C Core Objective. Second, PRM provides the basis for broadening the scope of product-related risk management to encompass all aspects of product development and marketing at J&J. Third, PRM will provide for the effective identification of product issues at the product team level (or its equivalent at J&J operating companies) enterprise-wide. Fourth, PRM establishes the Quality organization responsibility, from the product team up through the J&J CQO. This responsibility, as detailed below, includes monitoring the identification and assignment of responsibility for resolution of issues, the requirement to develop resolution timelines and action plans, appropriate documentation, and quality metrics for evaluating issue resolution, including tracking remediation of issues against established timelines, the escalation of issues to the appropriate level within the J&J organization and ensuring the sharing of best practices across the enterprise.

55. The PRM Standard will support the effective implementation of the J&J Quality Policy and Enterprise Risk Management ("ERM") Framework (described at Exhibit B, and at

Section VI.C. below), the Q&C Core Objective (set forth at Exhibit A and described above), and non-financial aspects of ERM at J&J. The PRM Standard provides for the design and implementation of critical enterprise-wide systems directly tailored to promote the identification, prevention and timely resolution of product issues and problems at the Company.

56. As noted above, I believe that the forward looking aspects of the PRM Standard will underpin the critical preventive component of the Q&C Core Objective (*see, e.g.*, ¶ 22 above) because product risk management is designed to operate at all levels of the enterprise, and will be directed where issues are likely to originate, and, if left unresolved, grow into bigger problems, potentially triggering reputational, regulatory and legal risks.

57. Crucial to the design of the PRM Standard, in my opinion, are the requirement for early identification of issues, the assignment of direct responsibility for resolution, the establishment of defined timelines for resolution, and the implementation of an escalation process that will provide a mechanism for independent notification and intervention through the Quality organization to ensure risk mitigation that will bring the appropriate resources and levels of responsibility to bear at the earliest possible time. I will discuss my views regarding each of these critical aspects of product risk management under the proposed settlement below.

2. Issue Identification and Assignment of Resolution Responsibility

58. To be effective, I believe that the PRM Standard must provide for assignment of operational responsibility, monitoring and escalation of open issues or identified action items as they occur and at the source of the issue, which will typically be at the business unit level and specifically within the product team that is assigned development and commercialization responsibility for the product over its life time. The product team (or its equivalent at each of J&J's operating entities) is comprised of representatives of functional areas relevant to all J&J

products and products in development. These functional areas include chemistry, manufacturing and controls (referred to as "CMC" herein), toxicology/drug metabolism and pharmacokinetics, clinical, regulatory, commercial, and project management.

59. The product team is responsible for the development of, and marketing strategy and operations associated with a product or suite of products at a pharmaceutical company.[7] The same product team typically manages this process from development to patent expiry, a process referred to as the life cycle. The PRM Standard will be designed and implemented at J&J to identify and resolve issues and/or problems that arise related to all aspects of drugs and products, in any of the above functional areas, and during pre- or post-marketing.

3. Role of the Quality Organization

60. The independent Quality organization will play a key role in the design and effective operation of PRM at J&J. First, under the proposed settlement, the CQO and the J&J Quality organization are tasked with responsibility for the design and implementation of the PRM Standard enterprise-wide at the Company, as well as for ensuring the adoption of implementing standards and SOPs at the sector levels. After the PRM Standard is in place, the

[7] To better understand the role each of these functional personnel play at the product team level, the following illustrative information is provided. Chemistry representatives assure that there is adequate material for pre-clinical testing, clinical trials and marketing, and that all such materials meet the specifications for release and use agreed with regulatory authorities. The toxicology and DMPK representatives develop validated assay that allow toxicologists, clinicians and pharmacovigilance experts to identify whether blood or tissue levels may be associated with enhanced risk, and therefore suggest maximum allowable exposures for patients. The clinical members of the product team, in conjunction with biometrics (statistics) and based on available data, will design and execute studies to enable the broadest use of products consistent with the label and the weight of evidence. Regulatory affairs representatives ensure that the Company is compliant with relevant regulations, and especially that the drug is used and marketed only in accordance with the approved FDA labeling. Marketing representatives are responsible to ensure that the product achieves the widest possible use consistent with the safety and efficacy profile of the drug or device, and to recommend clinical studies that would support a broader use.

independent Enterprise Regulatory Compliance Group and the J&J Quality organization will be responsible for ensuring it operates effectively. Pursuant to the PRM Standard, Quality personnel will be tasked with responsibilities at the product team level, including, in conjunction with project management, to ensure that a complete list of action items raised at the meeting is prepared, assigned responsibility for each action item is accepted by appropriate responsible functional area(s) within the team, and an action plan for resolution within established timeframes is developed. In addition, as discussed below, the Quality organization will play a critical role in the notification and escalation of issues within J&J. Finally, as discussed above, the CQO will provide reporting to the RCGC on the implementation and effectiveness of the PRM Standard, including about trends and metrics, in accordance with the Charter and the Operating Procedure. These responsibilities will ensure that an independent organization will place product quality, and the Q&C Core Objective, above all other considerations.

4. Establishment of Timeframes for Resolution

61. A crucial aspect of the PRM Standard is the imposition of established timeframes to ensure the timely resolution of identified issues and problems. In my opinion, the most important timeline metric will be the very first, the time assigned to establish a comprehensive action plan to address an issue that arises at any level of the enterprise. Such action plan will include identifying the functional responsibility to report back what is to be done, by whom, and what must be done to mitigate patient or enterprise risk in the interim. In my opinion, once the PRM Standard has been implemented at J&J, no longer will an issue be able to become sidelined, whether intentionally for commercial reasons or due to the lack of adequate tracking, and remain unresolved for indeterminately long periods of time. To ensure unresolved issues are dealt with in a timely manner, failure to comply with established timeframes will result in the

escalation of unresolved issues up the J&J organization, both within the Quality organization and line management of the responsible and identified function. Appropriate personnel within the Quality organization will sign off on timelines set in accordance with standards and SOPs, and the CQO will report quarterly to the RCGC on the progress of this process. Individual timelines will reflect the work that must be done, *e.g.*, if a clinical trial must be done, the timeline will reflect not only the time it takes to perform this trial but also the interim activity designed to protect patients, providers and the enterprise.

5. Escalation under the PRM Standard

62. Escalation as provided for pursuant to the PRM Standard will include both notification and escalation. Notification will include that a problem has been identified, resolution responsibility assigned and timelines established for a plan of remediation and action steps. Such notification will occur both up the relevant functional lines, for example, if resolution responsibility for an issue is assigned to the chemistry function, notice will go up the chemistry chain, as well as separately up the independent Quality organization, from the Quality personnel with responsibility at the product team level, through the operating entity and sector levels to the J&J CQO, as appropriate.

63. Second, resolution responsibility for the issue or problem will be elevated within J&J's organization if established timelines pass without resolution, or a determination is made earlier that resolution will require authority or resources that can only be brought to bear at a higher level. For example, in the case of Risperdal, the widespread use of atypical antipsychotics in elderly patients with dementia may have led to an early decision to promote Risperdal for this purpose. Commercial success would provide a major driver for continued practices, even if they appeared to "cross the line" to off-label promotion.

64. In my opinion, had PRM been in place, regulatory affairs, clinical affairs and pharmacovigilance representatives to the product team for Risperdal would have identified rising prescriptions for the elderly demented without adequate supporting clinical data as an issue based upon one of a number of possible signals long in advance of an FDA "shot across the bow." The bases for this being identified as an issue under PRM could have included, for example, an emerging pharmacovigilance database for older institutionalized patients (an unstudied population); a proposal from key opinion leaders or a professional society to clinical affairs to provide data from randomized clinical trials in this population, or a regulatory warning to a competitor for similar off-label activity. Under PRM, an action plan for resolution of the identified issue against established timelines would have been developed. This action plan could have proposed as remediation steps conducting a clinical trial, enhanced pharmacovigilance (such as a registry of elderly Risperdal users) or a review of promotional activities, or a combination thereof. Moreover, PRM would have required escalation, to, among others, the CQO and through her to the Board as appropriate, should the issue not be resolved within established timeframes.

65. As an element of the Core Objective and the PRM standard, the process of issue identification, appointment of responsibility and resolution will be documented and presented regularly by appropriate officers and executives with oversight responsibility at the corporate level. The standards and SOPS signed off by the CQO will require specificity in assigning responsibility, approval of the plan and the steps to mitigation of risk. In areas of patient safety, the CMOs will join the CQO and CCO in reporting to the Board. Quality metrics will include time to resolution as the basis for continuous improvement.

66. In my opinion, assets acquired from smaller companies, for the reasons detailed above, are an area especially likely to generate issues under product risk management within J&J. The PRM Standard is ideally suited for the rapid identification (whether internally or eternally) of such issues, the time-sensitive generation of action plans to address them, and the management of the use of such products in an ethical and compliant manner pending the resolution of the issue, or its escalation up the J&J organization. For example, under PRM, the acquisition of SCIOS would have required an action plan be put into place rapidly either to abandon outpatient dosing, or to define a clinical trial program to support outpatient dosing with interim safety action. Should J&J acquire Chinese companies (*see, e.g.*, "J&J Targets China Acquisitions for Mental Disease Drugs;" *Bloomberg News* - May 16, 2012), PRM will require in-depth planning that goes beyond Supply Chain into the quality of R&D, and the documentation to J&J standards of safety and effectiveness of acquired assets.

6. Independence of PRM

67. The role and responsibilities of the independent Quality organization in connection with the PRM Standard, as described above, will help assure that the identification, monitoring, and escalation of issues are not unduly influenced by the pressures of research, development or marketing priorities. Pharmaceutical companies like J&J are in the business to make a profit, typically by delivering a product "on time and on budget." Therefore, when issues arise with the potential to affect the Company's ability to do this, whether at the product team or business unit level, it is critical that the tasks of monitoring and escalating such issues through to resolution be managed independently of any such considerations. Quality employees

are independently compensated,[8] based on evaluation within the Quality organization and strictly against their quality and compliance responsibilities, goals and objectives, and associated standards under the Quality Framework and Policy.

68. In my view, this independence of action provides a crucial check and balance for J&J product risk management. For example, when a potential new safety signal arises during the early marketing of a novel product, such findings are regularly shared at the product team. Pursuant to the PRM Standard, identified issues will be the subject of an action plan, and addressed according to established timelines, and that independent QA monitoring of the product risk management process will ensure that such issues are fully addressed in a timely manner. Attempts to ignore or sideline problems identified under the PRM Standard will be quickly identified and reported through independent Quality channels to the CQO, as appropriate, rather than potentially being recycled endlessly at the product team or operating entity level.

7. The Sharing of Best Practices under the PRM Standard

69. Finally, product risk management under the proposed settlement will result in the active sharing of best practices across J&J and its decentralized organizational structure. Pursuant to the implementation of the PRM Standard at J&J, new processes will be developed to better prevent problems and issues from arising in the first place, or to speed their identification and resolution should they arise. The PRM Standard will ensure open and two-way communication up and down the J&J organization of such best practices as they are developed, and require their being actively shared across J&J's Sectors and operating entities. Since the

[8] It is my understanding that the compensation and performance reviews for approximately 75% of Quality personnel at J&J occur wholly within the Quality organization. For the remaining approximately 25% of Quality personnel, while business lines have primary responsibility regarding compensation and performance review, the basis for such determinations is performance of quality-related duties and responsibilities, and such determinations are subject to review by the CQO and Quality organization.

Board will be reviewing PRM activity regularly, there is added impetus for best practices, once recognized, to be actively supported in their promulgation throughout the enterprise. In my opinion, having the PRM Standard in place, a process that is owned by the independent Quality organization at J&J and under the direct oversight of the Board, with established standards and timelines for addressing issues as they arise, will result in the effective mitigation of product risk in an efficient and timely manner in the future, leading to decreased numbers of issues arising within J&J both because of early identification and remediation and the sharing and adoption by business units and product teams of best practices across the worldwide enterprise.

8. Implementation of the PRM Standard during 2013

70. In my opinion, the agreement to implement the PRM Standard during 2013 is significant. Implementation of PRM at J&J will require a cultural change, including the acceptance by product team members of the responsibilities of Quality to ensure, among other things, that all issues are identified, monitored and tracked to resolution. PRM has important resource implications, including ensuring the availability of adequate numbers of properly trained Quality personnel. PRM must be promulgated and promoted enterprise-wide, which is especially challenging given the decentralized nature of J&J, and the broad scope of products across pharmaceuticals, biologics, devices, diagnostics, and over-the-counter preparations. In light of the magnitude of the effort the implementation of the PRM Standard will entail at J&J, the Company's commitment to have completed this implementation during 2013 is significant.

V. EXHIBIT B GOVERNANCE ENHANCEMENTS AND CHANGES UNDER THE PROPOSED SETTLEMENT

71. In my opinion, Exhibit B reflects J&J's recognition that for certain areas of corporate activity the decentralized structure that existed during the period of the alleged wrongdoing is inadequate to avoid or mitigate risk. The Company further recognizes the role of

the Board in connection with corporate oversight and control. The Company has gathered these principles under its Enterprise Risk Management ("ERM") reforms, taken initial steps to strengthen the role of the CQO and the CCO, created a global Supply Chain, and sent a message throughout the enterprise that the sectors and business units must act in accordance with the newly established Quality Framework and Policy. ERM, in my opinion, reflects progress towards Board oversight of risks within J&J. Adoption of the ERM Framework ensures that all levels of J&J, from corporate down to business units, are aligned with respect to key areas of finance, law, and compliance, and utilize common tools such as objective setting, risk identification, assessment and response, communication and monitoring. However, from a product point of view, Supply Chain under ERM addresses only issues around manufacturing and distribution.

72. In my opinion, the Supply Chain initiative reflects an improvement in J&J culture and recognition of the importance of Quality Assurance at the Company. The Supply Chain provides for an enterprise-wide standardization of the procurement and distribution of J&J products internally and externally. The Supply Chain initiative shows that J&J can adopt more far-reaching provisions, such as the PRM Standard, within existing functional structures and without fundamentally changing the decentralized structure of J&J. The Supply Chain initiative establishes the role of Quality as an independent organization reporting through to the CQO, and strengthens the role of the CQO, as described above. In order to accomplish this enterprise-wide set of Standards, J&J has instituted the Quality Policy and Framework and its first set of such Standards.

73. Under this Quality Framework the Company recognizes "that all staff in Quality and Regulatory Compliance functions worldwide have a reporting relationship to the J&J CQO"

(Section II.C.3.a.), thereby ensuring, among other benefits, that the Quality organization maintains it independence, in performance review, promotion and compensation, from commercial or other line management pressures at J&J. The Quality Policy provides the framework, in conjunction with the Quality and Compliance Core Objective, for establishing enterprise–wide Standards to enhance quality and compliance throughout the enterprise. The enterprise level Standards will be the basis for writing standards at the Sector and business unit level, each of which will comply with the enterprise-level standards which are established first. For example, as noted above, PRM will be adopted as a Standard under the Quality Policy in the proposed settlement (Exhibit A) and become the basis for PRM at the enterprise, sector and individual business unit levels.

VI. THE SETTLEMENT COMMITMENT TERM AND FUNDING PROVISIONS

74. Under the proposed settlement, the Company agrees to maintain the provisions of the settlement, including all of the provisions set forth in Exhibits A and B, for a period of not less than five years from the Effective Date of the settlement (the "Settlement Commitment Term"). *See* Stipulation, ¶ 2.3.

75. The Company also agrees that for the Settlement Commitment Term "it will spend such funds as are necessary to implement and maintain the provisions set forth in Exhibits A and B attached hereto." *Id.*, ¶ 2.2. The Company further agrees and commits that during the Settlement Commitment Term, "the J&J Chief Quality Officer or J&J Chief Compliance Officer have discretion to make funding recommendations directly to the Board or an appropriate committee of the Board." *Id.*

76. The funding provision is important in my opinion because there are a number of provisions, including the adoption of new standards and their subsequent promulgation

throughout the enterprise that will incur allocation or re-allocation of resources, consisting of people, time and money. The funding commitment also ensures that should a determination be made that the activity of the CCO or the CQO, or any other key member of management is inadequately resourced, the Company has committed to ensuring necessary resources to guarantee that these key members of management can meet their obligations, and that improvements in the J&J systems can be realized consistent with the Q&C Core objective, Quality Framework and Quality Policy.

77. In my opinion, to have any lasting impact on a company's corporate culture, it is necessary for there to be a clear and unambiguous signal from the Board and senior management regarding the importance of such provisions, a firm commitment to ensure their adequate funding going forward, and a mechanism to evaluate these signals and resources over an adequate period of time.

78. The Settlement Commitment Term and funding obligations under the proposed settlement do this in a meaningful way. Based on my experience in the pharmaceutical industry, I believe that after a five year period during which the Governance Reforms set forth in Exhibit A are actively implemented, funded and transparently shared, they should be thoroughly ingrained into J&J's normal operating procedures and corporate culture.

VII. CONCLUSION

79. In my opinion, the provisions of the settlement, executed in good faith, represent a substantial benefit to J&J and its shareholders and places J&J at the forefront of product risk management issues in the pharmaceutical industry. If fully adopted and executed, the governance and compliance reforms reflected in the proposed settlement will help to establish best-in-class practices at J&J, designed to prevent, detect and resolve potential violations of law,

regulations, or company policies. The Q&C Core Objective, its ownership at the level of the Board, and the direct reporting of quality, compliance and product-related issues and resolutions to the Board will put J&J once again at the forefront of pharmaceutical companies. Product Risk Management, as a new enterprise-wide Standard for J&J within its independent Quality organization, should provide far-reaching benefits to J&J across its broad portfolio of healthcare products.

80. I believe that these provisions, particularly when combined with the other substantive reforms, enhancements and changes set forth in Exhibit A and Exhibit B of the proposed settlement, should enable J&J to regain its status as one of the nation's most admired companies, and to provide meaningful products that save lives and improve the quality of life for patients and their families.

August 24, 2012

MITCHELL GLASS

EXHIBIT 1

CURRICULUM VITAE

Mitchell Glass, M.D.

EDUCATION:

1973	B.A. Special Honors in Biology, University of Chicago
1977	M.D. University of Chicago

POSTGRADUATE TRAINING, FELLOWSHIP AND FACULTY APPOINTMENTS:

1977-83	Residency in Internal Medicine, Fellowship in Pulmonary Medicine and Post-doctoral fellowship in respiratory Physiology, University of Pennsylvania
1985-89	Assistant Professor Medicine and Physiology, U. of P Attending Physician, Pulmonary section, Graduate Hospital (Phila).

CAREER HIGHIGHTS:

- 4 NDAs and MAAs
- 7 pre-NDA meetings (and international counterparts)
- 7 end of Phase 2 Meetings
- >40 INDs
- Developed "from scratch" new integrated development teams in 3 companies
- Managed annual budgets from $<250,000 to > $150million

INDUSTRIAL EXPERIENCE

Present: Consultant to start-up pharmaceutical and device companies
CEO and Director, AVATAR Biosystems Incorporated
CMO and Director, OrphageniX, Inc (targeted gene alteration, oligonucleotide therapy))
Chairman, Clinical Advisory Board of Topigen, Inc.

May 2005 – June 2008 CEO and Director Aqumen NA, Inc. (Japanese ophthalmic biotech);
Director Aqumen KK

October 2004 – June 2006 Chief Scientific Officer University City Science Center (Philadelphia PA)

May 2003 – June 2004 Director (Board) and president and COO of geneRx+

1997- 2002: Chief Medical Officer, SVP Strategic Drug Development, Clinical Development and Regulatory Affairs, AtheroGenics, Inc. Alpharetta GA

Responsibilities included:

- Managing annual budget that grew from $250,000 to > $20million
- Filing 5 INDs and acting as senior representative to HPFB and FDA
- Initial and subsequent clinical plans for AGI-1067, AGIX 4207 and AGI-1096
- Corporate Officer. Member of IPO Team
- Establishing and managing a new development department that grew from n =1 to 29, including Development Chemistry, Toxicology, ADME and Biometrics/Data Management, Clinical Research and Safety; Regulatory Affairs and Quality Assurance;
- Chairman of Pharmaceutical Review Board for integration of Research and Development

- Acting VP licensing and corporate development 3/01 to 6/02

Activities/accomplishments included:

- Out-licensing of diagnostic in-licensed in 1997; in-licensing second AGI platform (11patents around MEKK technology) from National Jewish MRC (Denver)
- Founding member of Executive Committee;
- Presenter to potential investors and negotiator with all potential corporate partners;
- Execution of 10 Phase 1 studies (3 NCEs);
- Successful completion and reporting of Phase 2 study (AHA plenary session)
- Advancement of second NCE into Phase 2 and 3rd NCE into licensing discussions,
- Presentation of first and second strategic plan for AGI to Board of Directors.
- Successful IPO of AtheroGenics, Inc (AGIX) August 00.
- AGI Chair of Joint Management Committee with Schering Plough for co-development of AGI-1067:10/99- 10/01 (dissolution of collaboration).

1997 Consultant in clinical research and development to biotech and public companies

1995-6 Vice President and Director CardioPulmonary (Pulmonary/Diabetes) Therapeutic Unit Clinical Research, Development and Medical Affairs, SmithKline Beecham Pharmaceuticals

Responsibilities included:

- Managing budget > $150 million and team of 55 FTEs (including 3 VPs)
- All aspects of phase 2 through 4 studies across a range of > 20 NCEs;
- Initial and subsequent clinical plans for NCEs (compound selection)
- Licensing diligence
- Providing strategic input as Senior Clinical Member of Cardiopulmonary TAT
- Filing NDA and MAA for TEVETEN, COREG (Heart Failure)
- Successful End of Phase 2 meeting and Phase 3 strategy for AVANDIA

1988-95 ICI Pharmaceutical Group and Zeneca PLC (Wilmington, DE)

Responsibilities included

- Managing budget that grew from $165,000 to > $30 million
- Filing 7 INDs and all aspects of phase 1 studies across a range of NCEs;
- Initial and subsequent clinical plans for ICI 204,219 (ACCOLATE)
- Developing, executing and reporting phase 2 studies for 5 pulmonary products
- Establishing and managing a new therapeutic team that grew from n =1 to > 30.
- Providing strategic input to all pulmonary and allergy projects
- International project Physician responsibility for ACCOLATE including Europe and Japan
- Preparation of NDA and MAA for ACCOLATE

1999- Faculty and course director PERI Course (DDMS-1) for doctors entering pharma

2004 – Director of PERI Course DDMS-1; developed course curriculum for early drug development

SPECIALTY CERTIFICATION:

1980	American Board of Internal Medicine
1984	Pulmonary Medicine (A.B.I.M.)

LICENSURE: PA MD 022820-E (inactive)

AWARDS, HONORS, AND MEMBERSHIP IN HONORARY SOCIETIES:

1980-81	Pennsylvania Thoracic Society Fellow
1982-83	American Thoracic Society Fellow
1984-87	E.L. Trudeau Fellow, American Thoracic Society
1973	Member, Sigma Xi
1980	Member, American Thoracic Society
1991	Member, American Academy Allergy & Immunology
1991-9	Member, Board of Directors, American Lung Association (ALA) of Delaware
1991-3	Chairman, Medical Awareness Subcommittee, International Pharmaceutical Aerosol Coalition (PACC/IPAC)
1993-96	Executive Board, American Lung Association (ALA) Delaware
1996-7	President - Elect Delaware Thoracic Society
1997-8	President, Delaware Thoracic Society
1997	Volunteer Excellence Award in Organizational Effectiveness; American Lung Association (National Leadership Meeting)
1997-8	American Lung Association (national) Research Coordinating Committee
1998	ALA Scientific Advisory Board; Volunteer Leader Task Force on Self Assessment and Strategic Planning
1999 -2001 ALA:	Member of Strategic Planning Committeee (responsible for creation of nationwide strategic plan adopted in 2001)
2002- 05	Board of Governors, University of Chicago. Oversight Committee for Alumni Affairs

ORIGINAL PAPERS:

1. Glass M, Kaplan JE, Macarak JE, Aukberg SA, Fisher AB, Serum fibronectin is elevated during normobaric and hyperbaric oxygen exposure in rats. Am. Rev. Respir. Dis 130:237-241, 1984.
2. Glass M, Sutherland MW, Forman HJ, Fisher AB, Selenium deficiency potentiates paraquat-induced lipid peroxidation in isolated perfused rat lung. J. Appl. Physiol. 59:619-622, 1985.
3. Sutherland MW, Glass M, Nelson J, Lyen Y, Forman HJ, Oxygen toxicity; loss of lung macrophage function without metabolite depletion. Journal of Free Radicals in Biology and Medicine 1:209-214, 1985.
4. Glass M, Forman HJ, Rotman EI, Clark JM, Pietra GC, Fisher AB, Bronchoalveolar polymorphonuclear leukocytes in pulmonary oxygen toxicity. J. Hyperbaric Medicine, 1:107-121, 1986.
5. Abrams WR, Kucich U, Kimbel P, Glass M, and Weinbaum G. Acute cigarette smoke exposure in dogs: the inflammatory response. Exper. Lung Res, 14:459-475, 1988.
6. Smith LJ, Geller S, Ebright L, Glass M, and Thyrum PT. Inhibition of leukotriene D_4-induced bronchoconstriction in normal subjects by the oral LTD_4, receptor antagonist ICI 204, 219. Am Rev Respir Dis, 141:988-992, 1990.
7. Bernstein JA, Greenberger PA, Patterson R, Glass M, Krell RD, and Thyrum PT The effect of the oral leukotriene antagonist, ICI 204, 219, on leukotriene D_4, and histamine-induced cutaneous vascular reactions in man. JACI, 87: 93-97, 1991.
8. Glass M. Early results with oral ICI 204,219. Annals New York Academy of Sciences, 1991:629143-147.
9. Glass, M. Feasibility of an outcome trial in the preventive therapy of emphysema. Annals New York Academy of Sciences, 624:195-208, 1991.
10. Glass M, Fisher AB, Alveolar lavage fibronectin in pulmonary oxygen toxicity. J. Hyperbaric Medicine.
11. Anthonisen N, Connnett J, Friedman, B, Glass M, Kilday DP, Mingo TS, Rudolphus A, Williams GW. Design of a clinical trial to test a treatment of the underlying cause of emphysema. AA NY Acad Sci, 624 Suppl: 31-34, 1991
12. Akers S, Kucich U, Swartz M, Rosen G, Glass M, Rosenbloom J, Kimbel P, Weinbaum G. Sensitivity and specificity of plasma elastin-derived peptides in chronic obstructive pulmonary disease. Amer. Rev. Respir. Dis, 145: 1077-1081, 1992.
13. Findlay SR, Barden JM, Easley CB, Glass M. Effect of the oral leukotriene antagonist ICI 204, 219 in antigen-induced bronchoconstriction in subjects with asthma. J Allergy Clin. Immunol. 89:1040-1045, 1992.
14. Ahn CM, Sandler M, Glass M, Saldeen, T. Effect of a synthetic leukocyte elastase inhibitor on thrombin-induced pulmonary edema in the rat. Exper. Lung Res., 19: 125-135, 1993.

15. Smith LJ, Glass M, Minkwitz MC. Inhibition of leukotriene D4-induced bronchoconstriction in subjects with asthma: a concentration effect study of ICI 204,219. Clin Pharmacol Ther, 54: 430-436, 1993.
16. Nathan RA, Glass M, Minkwitz MC. Inhaled ICI 204,219 blocks antigen-induced bronchoconstriction in subjects with bronchial asthma. Chest, 105: 483-488, 1994.
17. Spector SL, Smith LJ, Glass M. Effects of 6 weeks of therapy with oral doses of ICI 204,219, a leukotriene D4 receptor antagonist, in subjects with bronchial asthma. (ACCOLATE Asthma Trialists Group). Am J Respir Crit Care Med, 150: 618-623, 1994.
18. Donnelly AL, Glass M, Minkwitz MC, Casale TB. The leukotriene receptor antagonist, ICI 204,219 relieves symptoms of acute seasonal allergic rhinitis. Amer J Respir Crit Care Med, 151: 1734-1739, 1995.
19. Fish JE et al. Zafirlukast as therapy for mild to moderate asthma: a 13-week multicenter study. Clinical Therapeutics: 1997
20. Tardif JC et al. AGI-1067 and Probucol reduce post angioplasty restenosis after percutaneous coronary intervention. Circulation (accepted for publication).

ABSTRACTS (selected):

1. Blank J, Glass M, Glasgow J, Burdette LJ, Weinbaum G. Acute alveolar damage induces by exposure to NO_2. Amer. Rev. Respir. Dis. 133:85A, 1986.
2. Glass M, Akers S., Wederbrand KS, Fibronectin concentration in rats with altered sensitivity to hyperoxia. Amer. Rev. Respir. Dis. 135:A143, 1987.
3. Silverman S, Weinbaum G, Glass M, Alveolar permeability changes induced by acute exposure of rats to NO_2. Amer. Rev. Respir. Dis. 135:A143, 1987.
4. Silverman S, Oppenheim DM, Glass M, Weinbaum G. Neutrophil chemotaxis during the first twenty-four hours of exposure of rats to 30 ppm NO_2. Amer. Rev. Respir. Dis. 135:A94, 1987.
5. Nguyenpho HT, Haas K, Glass M. Effect of Vitamin E on occlusion and reperfusion arrhythmias and infarct size in canine model. Chest: 1990.
6. Glass M, Wade M, and Campbell EJ. The establishment of a library of patient samples to validate assays of elastase: antielastase balance. Amer. Rev. Respir. Dis. 143: A327, 1991
7. Nathan RA, Storms WW, Bodman SF, Minkwitz MC, and Glass M. Inhibition by aerosolized ICI 204,219, LTD_4 receptor antagonist, of allergen-induced bronchoconstriction. J. All. Clin. Immunol. 87: 256, 1991.
8. Smith LJ, Glass M, Miller CJ. Effect of oral ACCOLATE (zafirlukast) on leukotriene D4 (LTD4)- induced bronchoconstriction in patients with asthma. Amer J Respir Crit Care Med 151: A378, 1995.
9. Calhoun WJ, Lavins BJ, Glass M. Effect of ACCOLATE (zafirlukast) on bronchoalveolar lavage fluid (BAL) after segmental antigen bronchoprovocation. Amer J Respir Crit Care Med 151: A42, 1995.

10. Glass M, Snader LA, Israel E. Effect of the inhaled LTD_4 receptor antagonist ICI 204,219 on cold air-induced bronchoconstriction in patients with asthma. J Allergy Clin Immunol 93: 295. 1994.
11. Spector SL, Miller, CJ Glass M, et al. 13-week dose-response study with Accolate (zafirlukast) in patients with mild to moderate asthma. Amer J Respir Crit Care Med 151: A379, 1995.
12. Kemp JP, Glass M, Minkwitz, MC. Onset of action of the leukotriene-receptor antagonist zafirlukast (ACCOLATE) in patients with asthma. J Allergy Clin Immunol. 95: A844, 1995.
13. Nathan, RA Glass M, Snader LA, et al. Effects of 13 weeks of treatment with ICI 204,219 (ACCOLATE) or sodium cromolyn (INTAL) in patients with mild to moderate asthma. J Allergy Clin Immunol. 95: A990, 1995.
14. 15 and 16 on AGI-1067 and CART-1 (Circulation 2001 and 2002)

EDITORIALS:

1. Fisher AB, Forman HJ, and Glass M, Mechanisms of pulmonary oxygen toxicity Lung.162:255-259, 1984.
2. Glass M, Karnovsky M, and Fishman A. Oxygen Free Radicals. Proceedings of NIH symposium Dec 10-12, 1986 Summary of Frontiers in Basic Sciences that Relate to Heart, Lung and Blood Diseases Symposium. (published by NIH).

INVITED TALKS (selected)

New York Academy of Science .Early results with ICI 204,219 (NYAS). London, UK. October, 91:
NYAS . Testing novel therapy in preventing emphysema) Orlando, FL May, 91
Eighth Intl Conference on prostaglandins. ICI 204,219; Montreal, Can. July, 92
American Thoracic Society Evening Symposium. Miami, FL May, 92
IBC conference New drugs for asthma (Chairman) Washington, D.C. October, 92
National Asthma Education Prog. Workshop Chair. CFC's. Washington, Dec 92
AAAI Clinical Research Coordinators' Course Chicago, IL March 93.
Eur Respir Soc. (ERS) ICI 204,219 Florence, Italy September, 93
Interasthma. Results with zafirlukast. Jerusalem Israel, October 1993
American Thoracic Society. Evening Symposium Boston MA May, 1994
Eur Respir Soc. Compliance with novel oral therapy. Nice, France October, 94
First global symposium on asthma: Plenary talk on new therapy for asthma. Chicago, IL July, 95
ERS. Symposium Chairman. Role of pranlukast in pediatric asthma Stockholm. September, 1996
Marcel Dekker Publishers: Role of 5-lipoxygenase products in asthma (Puerto Rico March, 1997)
Conference organizer: "When zero percent is not enough; Atherosclerosis treatment in the era of coated stents" (Symposium associated with ACC Meeting; symposium proceedings accepted for publication). : March, 2002
Regulatory framework for establishing a US subsidiary for Japanese Pharma co.: December 2005

Early Stage East: panelist on venture capital: the entrepreneur's perspective May 2008